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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,339	12/20/2001	Michele Fiscella	PT124P1	8005

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,339	FISCELLA ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. *Claims* 1 - 22 *are pending.*

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. The following is noted:

The claims recite twelve nucleotide sequences referred to as SEQ ID NO:X, which are included in ATCC deposits No. Z and encode polypeptide of SEQ ID NO:Y, as listed in Table 1, pages 117 – 118 of the specification. It appears that these sequences possess different structures and distinct nucleotide sequences, which encode distinct proteins or peptides.

In the absence of any recitation in the claims or any direction in the specification to the contrary, the restriction of the twelve sequences encompassed by SEQ ID NOS:X is set forth as separate groups irrespective of the format of the claims.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups I – XII. Claims 1 – 10 and 14 – 15, drawn to an isolated nucleic acid molecule according to one of SEQ ID NOS in column 5 of Table 1, as well as to the corresponding vector, host cell, and method of producing a polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

Groups XIII – XIV. Claims 11, 12, and 16, drawn to an isolated polypeptide according to one of SEQ ID NOS in column 10 of Table 1, classified in Class 530, subclass 350.

Groups XV – XXXVI. Claim 13, drawn to an isolated antibody that binds to an isolated polypeptide according to one of SEQ ID NOS in column 10 of Table 1, classified in Class 530, subclass 387.1.

Groups XXXVII – XXXXVIII. Claim 17, drawn to a method of preventing, treating, or ameliorating a medical condition by administering a polynucleotide according to one of SEQ ID NOS in column 5 of Table 1, classified in Class 514, subclass 44.

Groups XXXXIX – LX. Claim 18, drawn to a method of diagnosing a condition by determining the presence of a mutation in a polynucleotide according to one of SEQ ID NOS in column 5 of Table 1, classified in Class 435, subclass 6.

Groups LXI – LXXII. Claim 19, drawn to a method of diagnosing a condition by determining the amount of expression of a polypeptide according to one of SEQ ID NOS in column 10 of Table 1, classified in Class 435, subclass 7.1.

Groups LXXIII – LXXXIV. Claims 20 and 21, drawn to a method for identifying a binding partner, or screening for molecules which modify activities of a polypeptide according to one of SEQ ID NOS in column 10 of Table 1, classified in Class 436, subclass 501.

Groups LXXXV – LXXXXVI. Claim 22, drawn to a method of preventing, treating, or ameliorating a medical condition by administering a polypeptide according to one of SEQ ID NOS in column 10 of Table 1, classified in Class 514, subclass 2.

5. Groups I – XII, XIII – XXIV, and XXV – XXXVI are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties and require non-coextensive searches, therefore each product is patentably distinct.

Groups XXXXIX – LX and LXI – LXXII are different methods. They differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Groups XXXVII – XXXXVIII and LXXXV – LXXXXVI are different methods. They differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Groups (XXXVII – XXXXVIII and LXXXV – LXXXXVI), (XXXXIX – LX and LXI – LXXII), and groups LXXIII – LXXXIV are different methods. A method of preventing or treating, a method of diagnosing, and a method of identifying binding partners differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I – XII and groups XXXVII – XXXXVIII, as well as groups I – XII and groups XXXXIX – LX *are related as product and process of using.* The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated nucleic acid molecules of groups I – XII can be used in PCR reactions in addition to method of preventing (groups XXXVII – XXXXVIII) and diagnosing (groups XXXXIX – LX) a medical condition.

Groups XIII – XXIV and LXI – LXXII, XIII – XXIV and LXXIII – LXXXIV, and XIII – XXIV and LXXXV – LXXXXVI *are related as product and process of using.* The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an isolated polypeptide of groups XIII – XXIV can be used for crystallography in addition to methods for diagnosing (Groups LXI – LXXII), identifying a binding partner (groups LXXIII – LXXXIV), or preventing a medical condition (groups LXXXV – LXXXXVI).

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

9. Claims 17 – 19 and claim 22 contain recitations of a "medical condition" or "pathological condition," while the specification discloses an extensive list of various medical and pathological conditions, at least on pages 225 – 297. In the event that an Invention containing any of the above claims is elected, and specific "conditions" are introduced into the claims during prosecution, additional species election will be required.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

July 20, 2004

PHILLIP GAMBEL, PH.D
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7/21/04